

Remarks

Claims 1-7 and 9-14 were pending in this case. Claims 1-7 and 9-14 were rejected.

At the outset Applicants acknowledge that the restriction requirement has been made final and respectfully maintain that rejoinder of dependent Claim 8 upon Notice of Allowance is appropriate.

Claims 1, 2, 4, 7 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 30 of U.S. Patent No. 7,001,920 and Claim 41 of U.S. Patent No. 6,673,838. Without addressing the merit of the rejection, in order to facilitate the prosecution of the current case, Applicants acknowledge that a terminal disclaimer may be used to overcome a rejection for non-statutory double patenting upon a finding that all other rejections have been overcome.

Claims 1-7 and 9-14 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement because it was maintained that the specification does not teach a method of treating bulimia nervosa in a mammal. Applicants respectfully traverse the rejection.

To satisfy the written description requirement under 35 USC §112, first paragraph, Applicants must only show that a skilled artisan would be able to practice the instant invention without undue experimentation. Applicants respectfully maintain that one skilled in the art, with Applicants disclosure before him or her, would be able to practice the claimed invention without undue experimentation. For instance, Pope et al., cited by the Examiner, teaches the use of a variety of antidepressants for the treatment of bulimia and states that, "The dose and plasma levels of antidepressant required to treat bulimia seem to be the same as those required to treat major depression." Applicants' invention is the use of novel SNRI compounds for the treatment of bulimia by methods known to those skilled in the art.

Claims 1-5, 7 and 9-13 were rejected under 35 USC §103(a) as being unpatentable over Pope et al. in view of Schweizer et al. because it was maintained that one skilled in the art would have been motivated to substitute venlafaxine for another antidepressant in a method of treating bulimia. Applicants respectfully traverse this rejection.


As the Examiner has aptly noted, the medical treatment arts are highly unpredictable. Different antidepressants act via different mechanisms and one cannot predict whether or how a given antidepressant will work. For instance, Malhotra, J. Clin. Psychiatry, 63:9 (2002), enclosed herewith for Examiner's review, teaches that TCAs may work differently than venlafaxine noting that TCAs did not show effective control of overweight while venlafaxine showed effectiveness in both binge eating and overweight. In view of the foregoing, Applicants maintain that Claims 1-5, 7 and 9-13 are not made obvious in light of Pope in view of Schweizer.

Claim 6 was rejected under 35 USC §103(a) as being unpatentable over Pope et al. in view of Schweizer and further in view of Wang. Wang teaches that the disposition of venlafaxine enantiomers in humans is not stereoselective. Applicants point out that Claim 6 does not relate to stereoselectivity but rather defines the position of R₅ and R₆ on the phenyl ring relative to the point of attachment. Nothing in Wang overcomes the deficiencies of Pope and Schweizer described above and this rejection should be withdrawn.

Claims 1-5, 7 and 9-14 were rejected under 35 USC §103(a) as being unpatentable over Pope et al. in view of Edgren et al. Applicants respectfully traverse this rejection. Edgren teaches controlled release dosage forms. Edgren does not teach the use of venlafaxine for the treatment of bulimia. Nothing in Edgren supplies the deficiencies of Pope described above and this rejection should be withdrawn.

Claim 6 was rejected under 35 USC §103(a) as being unpatentable over Pope et al. in view of Edgren and further in view of Wang. Wang teaches that the disposition of venlafaxine enantiomers in humans is not stereoselective. As explained above, Applicants point out that Claim 6 does not relate to stereoselectivity. Nothing in Wang overcomes the deficiencies of Pope and Edgren described above and this rejection should be withdrawn.

In view of the foregoing, Applicants respectfully maintain that Claims 1-7 and 9-14 are in condition ready for Allowance and respectfully request an early and favorable Notice of Allowance.



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